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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,257	06/20/2003	Shanta M. Modak	A33432-A-PCT-USA-A (07005)	7493
21003	7590	12/21/2004	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			AZPURU, CARLOS A	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/600,257

Applicant(s)

MODAK ET AL.

Examiner

Carlos A. Azpuru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 26-63 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Receipt is acknowledged of the preliminary amendment filed 06/20/2003.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 21 and 22. are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,706,024 (US'024). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'024 claims a polymeric medical article which has been impregnated with a treatment solution comprising between 1 and 5 percent of chlorhexidine wherein the chlorhexidine consists essentially of a mixture of chlorhexidine free base and a chlorhexidine salt (see claim 1). The mixture of chlorhexidine free base and chlorhexidine salt Is in a 1:1 to 1:5 weight/weight ratio, wherein the total weight of chlorhexidine is between 1 and 10 percent of the weight of the impregnating solution (see claim 2). Solvent selected may be water, reagent alcohol, and tetrahydrofuran (see claim 2). There

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are no unusual and or unexpected results which would rebut prima facie obviousness.

Those of ordinary skill would have therefore expected similar therapeutic results from the use of the instantly claimed medical article. The instant claims would have been obvious given the claims of US'024.

Claims 1-24, 26-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 09/746,670 (US'670). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'670 claims an antimicrobial medical article by treating the polymeric article with a solution of one or more solvents and a mixture of chlorhexidine free base and a water soluble chlorhexidine salt, wherein the ratio of chlorhexidine free base and water soluble chlorhexidine salt in solution is between 1:1 to 1:5 (see claim 1) Solvents may include water, alcohol, tetrahydrofuran, dimethylsulfoxide, dimethyl formamide, N-methyl-2-pyrrolidone and mixtures thereof (see claim 3). Various mixtures of these solvents are set out in claims 4-7. The article may be a catheter. The water soluble chlorhexidine salt is set out as chlorhexidine diacetate in claims 11-13. The medical article is claimed as polymeric in claim 14. Polytetrafluorethylene is used as the polymer in claims 15-16. Antiinflammatory agents are added to the mixture at claims 17-19 at a concentration of between 0.1 and 5 percent (see claims 17 and 19). The methods of preparation involve similar steps of filling or soaking the article to expose it to the chlorhexidine solution.) Those of ordinary skill would have therefore expected similar therapeutic results from the

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use of the instantly claimed medical article. The instant claims would have been obvious given the claims of US'670.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 11-15, 17, 19-23, 26-30, 32-34, 38-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon et al (US 6,261,271).

Solomon et al discloses an anti-infective medical article comprising chlorhexidine bulk distributed throughout a polyurethane base layer which may additionally have a coating layer. The coating layer may be chlorhexidine permeated and may also contain an antibiotic or antithrombogenic agent. A polymeric surface layer may also be laminated to this base layer (see Abstract).

Preferred articles are polymeric, most preferably a hydrophilic polymeric vascular catheter (see col. 4, lines 6-7). The melt extruded composition may contain about 0.05 to 10%, preferably about 1 to 5% by weight chlorhexidine, and may be prepared in any suitable way (see col. 4, lines 56-61). The article may be steeped in a solvent solution of chlorhexidine in order to permeate the polymer. An effective coating of chlorhexidine

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may be obtained when steeping a solution which contains from about 1-25%, preferably 5-15% chlorhexidine. The choice of solvent depends on the method of coating and the temperature of the steeping solution. Suitable solvents for this solution include water, methylene chloride and methanol. For chlorhexidine salts such as hydrochloride, acetate or gluconate, the suitable solvents are methanol, ethanol and water. Steeping may be carried out for about 2 mins to 2 hours at a temperature of about 15 to 60 deg. C. It is therefore evident that coating of the medical article may occur at any portion, depending on which section of the article is steeped in the chlorhexidine solution. Solomon does not disclose that the weight ratio of chlorhexidine free base to chlorhexidine salt is between 1:1 to 1:5. However, since both are contemplated by Solomon et al, those of ordinary skill would have found it within their skill to optimize the concentration of these known components of the solution of Solomon et al in order to obtain the coating which is instantly claimed. Barring unexpected results, there is not showing that the claimed criticality is not a mere optimization of a known composition used for the same art recognized purpose. The instant claims would have been obvious given the disclosure of Solomon et al.

Claim 25 is objected to as dependent upon a rejected base claim.

It is noted that serial number 09/618,432 may involve some double patenting issues, however the claims of that case were unavailable for examination at this time. Applicant is requested to forward a copy of those claims for review.

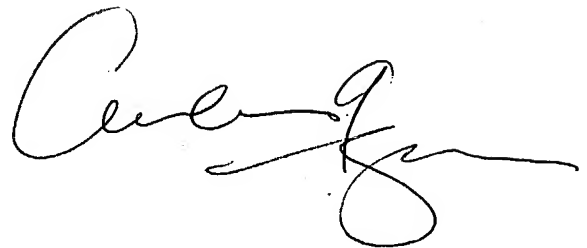
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ca

A handwritten signature in black ink, appearing to read 'Carlos A. Azpuru', with a stylized, flowing script.

CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500